RADIOBIOASSAY LABORATORY:	
GENERAL	Accept
 Documented, signed, approved, and controlled procedures are established for each step in the activities used to determine radioactivity concentrations or total radioactivity results for indirect radiobioassay and direct radiobioassay measurements. The procedures include: Sample preparation and radiochemical analyses, Data reduction, and Data reporting. 	
2. The facility/program implements an appropriate, documented QC program.	
3. The facility/program has designated a person responsible for reviewing QC data.	
4. Responsibility for review of all direct and indirect radiobioassay data rests with the individual who has technical responsibility for the program.	
PERSONNEL	Accept
1. The functional organization is consistent with the current organizational chart for the radiobioassay laboratory.	
2. The qualifications of the individual who has technical responsibility for the radiobioassay program is consistent with the position description.	
3. The individual who has technical responsibility exhibits adequate technical knowledge and management control for the program.	
4. The responsibility for maintaining and revising the QA manual or QA Plan is clearly assigned.	
5. The qualifications of the individual who has responsibility for the radiobioassay QA Program are consistent with the position description.	
6. Assigned responsibilities for the technical areas addressed in the training program are appropriate for the assigned positions	
7. All radiobioassay program staff are familiar with and can implement the documented QC program.	
8. The responsibility for major equipment maintenance and measurement system calibrations is clearly assigned.	
 9. Specialized skills required to conduct all protocols are documented annually and are included in the training program for individuals who conduct the protocols. The training includes: a period of close supervision until competency is demonstrated, a mechanism for evaluating and informing staff members of the adequacy of their performance in conducting assigned protocols, and a mechanism for retraining on a periodic basis and for correcting any deficiencies in performance between retraining. 	
10. Staff have adequate training and experience with the measurement systems and specific analyses they are assigned to perform.	
11. A record of training courses completed by each staff member is available for review.	
12. A record of the dates and findings of competency reviews is available for review under program management supervision.	

EQUIPMENT AND FACILITIES	Accept
 A list and description of the facilities and measuring equipment used in all the systems and protocols for which accreditation is requested is available in the facility. The list allows measurement systems with maintenance logs to be correlated with calibration records. 	
 Procedures are established for replacing or bringing spare equipment into routine service, repairing equipment on a rapid-response basis and/or using the services of another DOELAP-accredited laboratory to ensure continuity of service when systems or personnel fail to perform as required. 	
3. Adequate procedures and/or quality controls are in place to ensure the performance of measurement equipment to the levels of precision and accuracy defined by the laboratory for each measurement protocol. The procedures to be implemented when the equipment fails to meet these criteria are documented.	
4. To help in evaluating the stability of equipment performance, records of preventive maintenance and repair activities are available for each piece of critical measurement equipment.	
5. Continuity of equipment operation is adequately provided for through service contracts or through an in-house capability to maintain equipment and stock parts.	t
6. Relevant environmental parameters in the counting facility, such as counting room background measurements, are measured and recorded.	
7. The calibration of equipment is verified at regular intervals determined by equipment type, manufacturing specifications, accumulated stability data, or some other reasonable plan to demonstrate the reliability of the measurements performed by the processor.	
CALIBRATION	Accept
1. Calibration and verification practices for measurement equipment or systems are described in a procedure(s). The procedure(s) identifies the calibration services, reference materials, calibration intervals, and measurement assurance programs used.	
 2. Calibration and verification records for major equipment used in radiobioassay analyses include the following: equipment name or description manufacturers name model, style, serial number, or other identifying mark identification of all equipment variables requiring calibration or verification range of energy and nuclides (or concentrations) used for calibration allowable error (taking into consideration instrument tolerance) to coincide with the requirements of each protocol date and result of last calibration/verification, including assessed uncertainty of measurement identification of staff member or position responsible for equipment calibration, or of external service performing calibrations identify of reference standard and how the individual radiobioassay calibration data relate to national standards or nationally accepted measurement systems 	
 Radionuclide standards or calibration phantoms used for equipment calibrations and to test the accuracy of analytical procedures and/or measurement equipment are designated as Standard Reference Material (SRM) by NIST, Transfer Reference Standards (TRS), or standards directly compared with an appropriate SRM. Care is taken to maintain a standard source geometry. 	
4. Calibration procedures used are appropriate for the radionuclides of interest.	
5. Calibrations of <i>direct radiobioassay</i> measurement systems are performed with known sources of radionuclides incorporated in a suitable simulation of the body or the body part of interest, or with techniques that are technically equivalent. These calibration phantoms should have radioactivity incorporated uniformly throughout the organ of interest or the simulated body. Calibration phantoms should be anthropomorphic representations of appropriate geometries of the body whenever feasible.	
6. For each measurement system, a calibration is performed for the specific geometry and radionuclide or energy range for which accreditation is requested.	
7. The Laboratory strives to maintain system performance (check source measurements) within the range of ±10% at the 95% Confidence Level (1.96 F) of the established value for the check source.	

QUALITY ASSURANCE	Accept
1. A documented, approved quality assurance (QA) plan is in place, and addresses the following aspects of quality assurance: organizational structure, management and operational responsibilities instructions and procedures, including procedure validation qualification and training of laboratory personnel document control procurement of materials identification and control of material and samples (chain of custody) inspection and testing of material and equipment control and maintenance of calibration standards corrective actions review of procedures, specifications, and operating logs observation of operations and evaluation of quality control data quality assurance records documentation of detector capabilities, detector background checks, relative bias, relative precision, and methods of calculating results for periodic quality control determinations records management including any deviation from the use of established procedures, equipment, or facilities verification, validation, and documentation of computer software used for calculations documentation of specific customer requirements.	
2. Internal QA assessments on the use of written procedures are performed at least annually.	
Procedures are reviewed at least once every two years.	
The QA plan includes practices for ensuring staff competency.	
The QA plan describes the training program used to prepare staff to conduct assigned tasks (procedures), and for retraining staff when assignments or procedures are revised.	
6. Equipment used to process biological samples is procured and used in conformance with the QA plan.	
 Results of the laboratory's participation in intercomparison programs or internal measurement assurance programs are consistent with requirements defined in the QA plan. 	
8. Open lines of communication are maintained between technical and supervisory staff.	
9. Quality control protocols for measurement systems are in place and include: use of traceable radionuclide reference standards performance checks of measurement systems instrument calibration intra laboratory analyses (e.g., known quantities, replicates, and blanks) participation in available inter-laboratory intercomparison comparison programs computational checks review of procedures, specifications, and operating logs observation of operations and evaluation of quality control data evaluating conformance to the performance criteria of ANSI N13.30 evaluating conformance with internal performance criteria set by the QA plan evaluating quality control data to ensure the long-term consistency of analytical results verification of Lc, MDA, and/or MDC determinations background counts blind samples measurement equipment controls such as humidity, cooling, and power fluctuation, if necessary.	
10. Laboratory staff are familiar with and implement the documented quality control program.	
11. An authorized laboratory staff member examines all daily QC results on a periodic basis, and takes timely action to correct any deficiencies before samples and sample residuals are discarded and results are reported.	
12. Quality control results are summarized on a quarterly basis.	

 13. Documented, signed, approved, and controlled procedures are established for each step in the activities used to determine radioactivity concentrations or total radioactivity results for indirect and direct radiobioassay measurements. The procedures include: Sample preparation and radiochemical analyses Data reduction Data reporting. 	
14. The facility participates in a recognized, documented QC program.	
15. The facility has designated a person responsible for reviewing QC data.	
DIRECT RADIOBIOASSAY CRITERIA	Accept
1. The bias and precision criteria of the DOE Technical Standard and the customer's Minimum Detectable Amount (MDA) requirements are met by the <i>Direct radiobioassay</i> measurement systems (detectors, electronics support, and shielding). The Lc and MDA are calculated by techniques as described in the DOE Technical Standard and the draft ANSI N13.30 standard (ANSI 1996)	
Personnel shower facilities are in close proximity to the direct radiobioassay laboratory.	
3. Measurement chambers are designed to mitigate claustrophobia (may include two-way communications, remote viewing, fail-safe doors, etc.).	
4. Measurement chambers have adequate ventilation. (The use of O_2 monitors is recommended)	
5. Contamination-free clothing is used or available while the subject is counted.	
6. The laboratory is located at an appropriate distance from areas where radioactive materials are processed, stored, or transported.	
7. Periodic evaluations of chamber background measurements and Minimum Detectable Amounts (MDAs) are made.	
8. Prior to the initial radiobioassay, an orientation briefing on the measurement process are explained to the subject.	
The laboratory staff recognize the potential for external contamination and are able to describe appropriate investigative techniques to confirm the type of the contamination (i.e., internal or external).	
10. The direct radiobioassay program is designed to minimize measurement uncertainties and biases.	
11. An estimate of the total propagated uncertainties for the important radionuclides at the facility has been generated and documented.	
12. Direct radiobioassay spectra and associated data are retained in a retrievable format.	
INDIRECT RADIOBIOASSAY CRITERIA	Accept
Practices for receiving, handling, and storing samples are consistent with provisions in the QA plan.	
A system is in use for identifying and tracking all samples within the laboratory.	
Sufficient information is included with the samples to analyze and track the sample.	
The number of quality control samples is at least 5 percent of the total number of samples analyzed.	
 Specific procedures to analyze biological samples from human subjects for assessment of excretion rates are validated and documented before being used. 	
6. The laboratory uses appropriate techniques to ensure proper identification and quantification of specific radionuclide(s), and are capable of separating interferences or resolving a mixture of radionuclides.	
7. The laboratory determines analytical results and propagated standard errors in appropriate units. The results include appropriate volume, recovery, and decay correction. The standard error of each result is calculated and includes propagation of the estimated measurement uncertainties (e.g., calibration counting, measurement of volume or weight, losses from chemical separations, transfer, operations, and impurities).	

REPORTS	Accept
 The direct radiobioassay report includes the following items: subject identification date, time, and nature of examination identification of radionuclide(s) for which the subject was analyzed and other radionuclides detected identification of specific measurement procedures quantification of the amount of radionuclide(s) (whether positive, negative or zero) of each radionuclide measured in each part of the body counted estimates of counting uncertainty and, if possible, the total propagated, uncertainty (which includes counting and other random and systematic uncertainties at one sigma) value of the Lc and a priori MDA, in units consistent with the results the net count rate and standard error for measurements made for the purposes of screening only, and not for a quantitative measurement the value of the customer specified or service laboratory action level for prompt notification (this may be documented in the QA plan and not appear in the report) the make and model (or other unique identifier) of equipment used the identification of the person responsible for the report. 	
 2. The indirect radiobioassay report includes the following items: sample identification, including: assigned number total volume or mass of sample submitted reference date(s), and time(s) of sample collection and analysis identification of radionuclide(s) for which the sample was analyzed and other radionuclides detected kind of sample (urine, feces, etc.) quantification of the amount of radionuclide(s) in the sample using the appropriate blank values, of radionuclide(s), whether positive, negative, or zero estimates of counting uncertainty and the total propagated uncertainty (which includes counting, other random and systematic uncertainties) at one sigma identification of specific measurement procedures value of the Lc and a priori MDA in units consistent with the results the value of the customer specified or service laboratory action level for prompt notification (this may be documented in the QA plan and not appear in the report), and make and model (or other unique identifier) of equipment used the identification of the person responsible for the report. 	
RECORD RETENTION	Accept
 The service laboratory retains, in retrievable form, records required by ANSI N13.30 for a minimum of 3 years or for a longer period of time as specified by federal, state, local, or contractual requirements. These records include: results of all quality control performance checks results of quality assurance audits radiobioassay equipment calibrations procedures by which the measurements were made, (Direct) including generic methods and examples of calculations (or Indirect) calculations and generic examples all data used in the determination of the (Direct) person's (Indirect) sample results, including measurement spectra training received reported results (specified above in REPORTS, Direct and Indirect, as appropriate). 	

Those DOELAP participants who obtain analysis of radiobioassay samples under contract with commercial agents, are subject to all the items in the assessment checklist that pertain to routine quality assurance and quality control. The following additional items also apply to those participants.

ADDITIONAL CHECKLIST FOR DOELAP PARTICIPANTS USING RADIOBIOASSAY SERVICES UNDER CONTRACT

DOELAP PARTICIPANT:	
RADIOBIOASSAY PROVIDER:	
GENERAL	Accept
 The contract between the radiobioassay servicing laboratory and DOELAP participant clearly establishes:: The methods of sample preparation and radiochemical analyses Data reduction techniques Results of intercomparison studies Criteria for reporting data. 	
The DOELAP participant establishes documented, signed, approved and controlled procedures for each step in the collection of samples for indirect radiobioassay, shipment of samples for analysis and dissemination of results.	
CALIBRATION	Accept
 Calibration and verification practices employed by the radiobioassay servicing laboratory are understood and documented by the DOELAP participant. 	
QUALITY ASSURANCE	Accept
 The radiobioassay servicing laboratory provides the DOELAP participant with sufficient QC and calibration data to assure that analytical results are accurate and samples were analyzed within the established envelope of quality. 	
2. The DOELAP participant demonstrates sufficient understanding of the provided services to identify and resolve anomalous analysis results.	
 The DOELAP participant conducts audits at least on an annual basis of the radiobioassay provider to assure that the servicing laboratory maintains established levels of quality and adheres to criteria in the servicing contract. 	
4. The DOELAP participant maintains a blind audit program for providers of indirect radiobioassay services.	